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Title: LATEX MEDICAL ARTICLES FOR RELEASE OF ANTIMICROBIAL AGENTS

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APPEAL BRIEF UNDER 37 C.F.R. §41.37

Sir:

As set forth in the Notice of Appeal and Pre-Appeal Brief Review Request submitted September 25, 2009, and the Notice of Panel Decision from Pre-Appeal Brief Review mailed January 12, 2010, Appellants hereby appeal the final decision of the Examiner mailed June 26, 2009 ("Final Office Action"), in the above-identified application rejecting Claims 1-23.

The fee under 37 CFR 41.20(b)(2) ($540.00) and the fee under 37 CFR 1.17(a)(2) ($490.00) may be charged to deposit account No. 50-1047. In addition, any deficiencies may be charged to deposit account No. 50-1047

Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the Examiner's rejection of the claimed subject matter.

I. REAL PARTY IN INTEREST

Boston Scientific Scimed, Inc. is the assignee of the present invention and the real party in interest.

II. RELATED APPEALS AND INTERFERENCES

No prior and pending appeals, judicial proceedings or interferences which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal are known to the Appellant.

III. STATUS OF CLAIMS

The presently pending claims are Claims 1-23, and Claims 1-23 are presented for appeal.

IV. STATUS OF AMENDMENTS

A final Office Action was mailed on June 26, 2009, rejecting Claims 1-23. The claims have not been amended subsequent to the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The invention is adequately described in Claims 1, 6, 21 and 22, the only independent claims on appeal.

1. A medical article that comprises an antimicrobial region, said antimicrobial region comprising release-modulating microparticles dispersed within a latex polymer, said release-modulating microparticles comprising an antimicrobial agent and being adapted to release the antimicrobial agent, wherein said microparticles comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed.

6. A medical article that comprises an antimicrobial region, said antimicrobial region comprising release-modulating microparticles dispersed within a latex polymer, said release-modulating microparticles comprising an antimicrobial agent and being adapted to release the

antimicrobial agent, wherein said antimicrobial region is vulcanized and wherein either said microparticles comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed.

21. A medical article that comprises an antimicrobial region, said antimicrobial region comprising release-modulating microparticles dispersed within a latex polymer, said release-modulating microparticles comprising an antimicrobial agent and being adapted to release the antimicrobial agent, and said release-modulating microparticles selected from the group consisting of microparticles that comprise an encapsulating region that surrounds a region comprising an antimicrobial agent and microparticles that comprise a polymer having an antimicrobial agent dispersed within said polymer.

22. A medical article that comprises an antimicrobial region, said antimicrobial region comprising release-modulating microparticles dispersed within a latex polymer, said release-modulating microparticles comprising an antimicrobial agent and being adapted to release the antimicrobial agent, and said release-modulating microparticles selected from the group consisting of microparticles that comprise an encapsulating region that surrounds a region comprising an antimicrobial agent and microparticles that comprise a polymer having an antimicrobial agent dispersed within said polymer, wherein said antimicrobial region is vulcanized.

Each of Claims 1, 6, 21 and 22 contains the following common elements:

a) a medical article – paragraph [0006]

b) that comprises an antimicrobial region – paragraph [0006]

c) said antimicrobial region comprising release-modulating microparticles dispersed within a latex polymer – paragraph [0006]

d) said release-modulating microparticles comprising an antimicrobial agent – paragraph [0006]

e) and being adapted to release the antimicrobial agent – paragraph [0006]

Claims 1 and 6 also each contain the following element:

a-1) wherein said microparticles comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed – paragraphs [0008]-[0009]

Claims 6 and 22 also each contain the following element:

b-1) wherein said antimicrobial region is vulcanized – paragraphs [0029] and [0033]

Claims 21 and 22 also each contain the following element:

c-1) said release-modulating microparticles selected from the group consisting of microparticles that comprise an encapsulating region that surrounds a region comprising an antimicrobial agent and microparticles that comprise a polymer having an antimicrobial agent dispersed within said polymer - paragraphs [0008]-[0009].

The present invention is advantageous in that medical articles are provided, which can reduce the potential for infection upon contact with the body of a subject. (See paragraph [0013]). Additionally, latex medical articles can be made in which the therapeutic agent is dispersed throughout the medical article (see paragraph [0014]) and which are able to release antimicrobial agent over a prolonged period of time (see paragraph [0015]). Finally, with the present invention it is possible to use a wide range of microparticle loadings in connection with the medical articles, with the amount of microparticle loading being, for example, in the range of from 0.1 to 40 wt% (see paragraph [0018]).

VI. GROUNDS OF REJECTION TO BE REVIEWED UPON APPEAL

The following grounds of rejection are presented for review:

A. The rejection of Claims 1-23 under 35 U.S.C. §103(a) based on UMEMURA in view of TROGOLO and MCGLOTHLIN.

VII. ARGUMENT

A. Rejection Under 35 U.S.C. §103(a) Based on UMEMURA in View of TROGOLO and MCGLOTHLIN

Claims 1-23-are rejected under 35 U.S.C. 103(a) based on Umemura et al. (U.S. Patent No. 4,902,503) ("UMEMURA") in view of Trogolo et al (U.S. Patent Application Publication No. 2003/0118664 ("TROGOLO") and McGlothlin et al. (U.S. Patent No 6,329,444) ("MCGLOTHLIN"). This rejection is in error and should be withdrawn

The present invention is directed to medical articles that comprise an antimicrobial region, which antimicrobial region comprises release-modulating microparticles dispersed within a latex polymer. The release-modulating microparticles comprise an antimicrobial agent and are adapted to release the antimicrobial agent. In particular, Claim 1 of the present invention provides:

> 1. A medical article that comprises an antimicrobial region, said antimicrobial region comprising release-modulating microparticles *dispersed within a latex polymer*, said release-modulating microparticles comprising an antimicrobial agent and being adapted to release the antimicrobial agent, *wherein said microparticles comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed.*

The other independent Claims (6, 21 and 22) as well as all dependent claims also contain the same feature "said antimicrobial region comprising release-modulating microparticles *dispersed within a latex polymer*" as well as the requirement of either (a) microparticles that comprise a core and an encapsulating layer surrounding said core or (b) microparticles that comprise a material (e.g., a polymer), within which the antimicrobial compound is dispersed.

In contrast to the present invention, the primary reference, UMEMURA teaches the use of dissolved silver and describes its compositions as:

> A first antimicrobial latex composition comprising a homogeneous blend of a natural rubber latex or a synthetic polymer latex and protein silver and a second antimicrobial latex composition comprising a homogeneous blend of a cationic natural rubber latex or a cationic synthetic polymer latex and a water-soluble silver compound, ...

(See Abstract) (emphasis added).

Further, in addition to the fact that the non-comparative Examples 1-7 in UMERURA use dissolved protein silver, UMEMURA's methods clearly describes its antimicrobial latex compositions as containing dissolved silver:

> This antimicrobial latex composition may be prepared by virtually any known method as in the case of the protein silver. For example, an aqueous solution of a water-soluble silver compound, particularly that having a high concentration of the water-soluble silver compound, may be directly added to a latex. (col.5, lines 20-25) (emphasis added)

More particularly, UMEMURA discloses two types of antimicrobial latex compositions:

1) The first type contains a homogeneous blend of a natural rubber latex or a synthetic polymer latex and protein silver (Abstract). This first type utilizes a latex, e.g., natural rubber

latex, and a silver protein complex, protein-silver, dissolved in the aqueous phase of the latexes. (See col.4, lines 45-48). It is important to note that this first type of antimicrobial latex composition requires the silver to be water soluble. (See the Abstract; and specification at col. 2, line 60; col. 4, lines 45-48; col. 4, lines 54-57; and col. 5, lines 54-56.) Thus, in contrast to the present invention, this first type of antimicrobial latex composition in UMEMURA does not describe a medical article comprising "release-modulating microparticles dispersed within a latex polymer" as claimed in the claims of the invention.

2) Similarly, the second antimicrobial latex composition component in UMEMURA comprises a homogeneous blend of a cationic natural rubber latex or a cationic synthetic polymer latex and a water-soluble silver compound (see Abstract). The second type uses a homogeneous blend of a cationic natural or synthetic rubber and soluble silver compounds, e.g., silver nitrate, among others. (See, e.g., Abstract; and specification at col. 4, lines 49-53.) As with the protein silver, the water-soluble silver compounds are dissolved in the aqueous phase. (See, e.g., col. 8, lines 41-42.) Thus, as with the first type of antimicrobial latex composition, the second type of antimicrobial latex composition in UMEMURA does not describe a medical article comprising "release-modulating microparticles dispersed within a latex polymer" as claimed in the claims of the invention.

In the Advisory Action, the Examiner states that UMEMURA is not being used for its teaching on microparticles, but rather for the point that "latex with silver within it is known as taught by [UMEMURA]". The Examiner has previously taken the position that the term "latex" as used by Applicant is far broader than the literal definition and encompasses the polymers of UMEMURA. This view, however, is irrelevant to the claimed invention. It must be noted that regardless of the definition of "latex", UMEMURA still does not describe a medical article comprising "release-modulating microparticles dispersed within a latex polymer" as claimed in the claims of the invention, much less either (a) microparticles that comprise a core and an encapsulating layer surrounding said core or (b) microparticles that comprise a material (e.g., a polymer), within which the antimicrobial compound is dispersed.

Additionally, Applicant wishes to point out that UMEMURA (col. 2, lines 18-31) recites that a latex, such as a natural rubber latex dispersed in water, is a highly unstable system. Consequently, when an aqueous solution containing a highly soluble silver compound is added to a latex at a high concentration in order to give a high silver concentration in the resulting matrix

material, the silver nitrate has been observed to break the system. Moreover, when silver carbonate, which has an extremely low solubility in water (see, e.g., Comparative Example 3, which employs a silver carbonate suspension), is added, the stable latex dispersion system is also broken and aggregation is observed. Therefore, it has been impossible to obtain a stable latex composition, regardless of the solubility of the silver compound.

UMEMURA attempts to solve this stability problem by its technique as described at col. 2, lines 62-68:

> Accordingly, the crux of the present invention resides in an antimicrobial latex composition prepared by blending silver protein with a natural rubber latex or a synthetic polymer latex, and in an antimicrobial latex composition prepared by blending water-soluble silver compound with a cationic natural rubber latex or a cationic synthetic polymer latex.

Because UMEMURA teaches the use and importance of silver protein and other water soluble silver compounds in its invention, UMEMURA clearly teaches away from water-insoluble forms of silver, including silver carbonate suspensions, and thus teaches away from release-modulating microparticles comprising an antimicrobial agent like that claimed. See MPEP 2141.02.VI ("Prior Art Must Be Considered In Its Entirety, Including Disclosures That Teach Away From The Claims") and the cases cited therein. Moreover, even assuming for the sake of argument that one were to substitute a water-insoluble form as proposed by the Examiner, there would be no expectation of success. See MPEP 2143.02 ("Reasonable Expectation of Success is Required.")

TROGOLO is added in an attempt to overcome the deficiencies in UMEMURA. In the Advisory Action, the Examiner repeats his point that TROGOLO "teaches that antibiotics may be encapsulated". TROGOLO explains that the "microcapsule comprising an inorganic antimicrobial agent" is "coated with a hydrophilic polymer." (See Abstract). TROGOLO also teaches the incorporation of antimicrobial microcapsules into a polymer matrix. (See paragraph 68).

TROGOLO, however, does not teach or suggest that the antimicrobial microcapsules can be dispersed in a latex polymer. In fact, TROGOLO does not appear to disclose any type of latex whatsoever. Contrary to the Examiner's position, the polymers of TROGOLO do not include the term "latex" even as it is used by Applicant. As defined in paragraph [0021] of the current specification, a "latex," is "an aqueous polymer dispersion." By "aqueous polymer

dispersion" is meant "a dispersion of polymer particles in a water-containing fluid." As indicated in a previous Office Action, the term "latex" as defined by Applicant is not restricted to a particular polymer; however, it does require "a dispersion of polymer particles in a water-containing fluid." Nothing of the sort is taught by TROGOLO.

TROGOLO actually teaches away from using latexes at paragraph [0081], where the advantages of thermal/melt processing are disclosed, which advantages may be considered unique to the process disclosed and essential to the enhanced antimicrobial functioning of the resulting articles. Thermal melt/processing is completely antithetical to latex processing, which is water based. See, e.g., MPEP 2141.02 VI ("Prior Art Must Be Considered In Its Entirety, Including Disclosures That Teach Away From The Claims") and the cases cited therein.

Thus, there is no reason that one skilled in the art would combine the antimicrobial microcapsules of TROGOLO with UMEMURA, especially since UMEMURA actually teaches away from such antimicrobial microcapsules by requiring the use of soluble antimicrobial agents, particularly silver, in order to avoid latex instability. See MPEP 2141.02.VI.

The rejection based on TROGOLO with UMEMURA relies on the combination of two references each of which does not teach the elements of the claimed invention and which, by reason of their individual subject matter are not combinable. Thus, at the very least, the combination would have been unwarranted by the disclosures in the references. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q 1125 (Fed. Cir. 1984), *Carl Schenk, A.G. v. Norton Corporation*, 713 F.2d 782, 218 U.S.P.Q. 698, 702 (Fed. Cir. 1983), *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959), MPEP 2143.01, last paragraph. Consequently, the rejection could only have been based on undue hindsight reconstruction of the references. MPEP 2142, second paragraph, *Akzo N.V. v. U.S. International Trade Commission*, 808 F.2d 1241, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied,* 482 U.S. 909 (1987), *Loctite Corp. v. Ultraseal Ltd.,* 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985).

Moreover, even if the references were combined, there would not be a reasonable expectation of success. For example, one of ordinary skill would not reasonably expect success in using the antimicrobial microcapsules of TROGOLO in the latex-based process of UMEMURA as proposed by the Examiner, because UMEMURA requires the use of a dissolved antimicrobial agent in order to avoid latex instability. Again, the combination of the teachings of

UMEMURA and TROGOLO is directly contrary to what one of ordinary skill would have done with any expectation of success. See MPEP 2143.02 and the cases cited therein.

The addition of MCGLOTHLIN to the combination of UMEMURA and TROGOLO likewise fails. MCGLOTHLIN describes:

> Medical devices of synthetic rubber are prepared from cis-1,4-polyisoprene by dip molding without the use of sulfur containing components. The devices have surprisingly favorable tensile characteristics . . . [and are] freely usable without causing the user to suffer Type I or Type IV allergic reactions that typically arise from contact with natural rubber.

(See Abstract)

MCGLOTHLIN also teaches medical devices of synthetic rubber prepared from cis-1,4-polyisoprene by dip molding without the use of sulfur containing components.

The relevance of MCGLOTHLIN, if any, to the current invention is remote. In the Advisory Action the Examiner again notes that MCGLOTHLIN has been relied on as merely showing that coating of medical devices through dip molding is established (such as using one of the polymers defined as a latex). There is no teaching in MCGLOTHLIN, however, pertaining to antimicrobials, either soluble or as microparticles. Like UMEMURA and TROGOLO there is nothing in MCGLOTHLIN that teaches or suggests "release-modulating microparticles disposed within a latex polymer," and, even more particularly, of "microparticles [that] comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed" as claimed. Thus, MCGLOTHLIN adds nothing relevant to the combination of UMEMURA and TROGOLO discussed above, especially since it contains no teachings whatsoever pertaining to antimicrobials, much less antimicrobial microparticles.

Thus, the combination of UMEMURA, TROGOLO and MCGLOTHLIN fails to give the currently claimed invention as recited in independent Claims 1, 6, 21 and 22 as discussed above as well as the remaining claims which are dependent on these independent claims with each and every limitation as described in the claims.

Conclusion

For at least these reasons, Appellant respectfully submits that the rejection of Claims 1-23 under 35 U.S.C § 103(a) as discussed above are in error and should be reversed, and that Claims 1-23 are patentable over the cited references.

Thus, in view of the above, it is respectfully submitted that reversal of the rejections of record is in order.

Respectfully submitted,

/ Rosemary M. Miano/

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VIII. Claims Appendix

1. A medical article that comprises an antimicrobial region, said antimicrobial region comprising release-modulating microparticles dispersed within a latex polymer, said release-modulating microparticles comprising an antimicrobial agent and being adapted to release the antimicrobial agent, wherein said microparticles comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed.

2. The medical article of claim 1, wherein said medical article is selected from gloves, finger cots, supply and drainage tubes, catheters, condoms and contraceptive diaphragms.

3. The medical article of claim 1, wherein said medical article is a balloon catheter.

4. The medical article of claim 3, wherein said antimicrobial region is a balloon sleeve.

5. The medical article of claim 1, wherein said antimicrobial region is heat cured.

6. A medical article that comprises an antimicrobial region, said antimicrobial region comprising release-modulating microparticles dispersed within a latex polymer, said release-modulating microparticles comprising an antimicrobial agent and being adapted to release the antimicrobial agent, wherein said antimicrobial region is vulcanized and wherein either said microparticles comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed.

7. The medical article of claim 1, wherein said microparticles comprise an encapsulating layer that surrounds a core comprising said antimicrobial agent.

8. The medical article of claim 1, wherein said microparticles comprise a core and an encapsulating layer surrounding said core, wherein said core comprises said antimicrobial agent, and wherein said encapsulating layer comprises a polymer.

9. The medical article of claim 1, wherein said microparticles comprise a polymer, and wherein said antimicrobial compound is dispersed within said polymer.

10. The medical article of claim 1, wherein said microparticles comprise an inorganic material, and wherein said antimicrobial compound is dispersed within said inorganic material.

11. The medical article of claim 10, wherein said antimicrobial compound is dispersed within pores of said inorganic material.

12. The medical article of claim 1, wherein said microparticles comprise a silver-containing ion exchange material.

13. The medical article of claim 1, wherein said microparticles are silver-containing zeolite particles.

14. The medical article of claim 1, wherein said antimicrobial agent comprises silver.

15. The medical article of claim 1, wherein said latex polymer is formed from a natural latex.

16. The medical article of claim 1, wherein said latex polymer is formed from a synthetic latex.

17. The medical article of claim 16, wherein said synthetic latex is a pseudolatex.

18. The medical article of claim 1, wherein said release-modulating microparticles have an average largest dimension, on a weight average basis, ranging from 0.1 to 100 microns.

19. A process for providing the antimicrobial region of claim 1, comprising: (a) providing a latex comprising said microparticles, (b) contacting said latex with a substrate, and (c) curing said latex thereby forming said antimicrobial region.

20. The process of claim 19, wherein said substrate is a mold that is dipped into said latex.

21. A medical article that comprises an antimicrobial region, said antimicrobial region comprising release-modulating microparticles dispersed within a latex polymer, said release-modulating microparticles comprising an antimicrobial agent and being adapted to release the antimicrobial agent, and said release-modulating microparticles selected from the group consisting of microparticles that comprise an encapsulating region that surrounds a region comprising an antimicrobial agent and microparticles that comprise a polymer having an antimicrobial agent dispersed within said polymer.

22. A medical article that comprises an antimicrobial region, said antimicrobial region comprising release-modulating microparticles dispersed within a latex polymer, said release-modulating microparticles comprising an antimicrobial agent and being adapted to release the antimicrobial agent, and said release-modulating microparticles selected from the group consisting of microparticles that comprise an encapsulating region that surrounds a region comprising an antimicrobial agent and microparticles that comprise a polymer having an antimicrobial agent dispersed within said polymer, wherein said antimicrobial region is vulcanized.

23. The medical article of claim 1, wherein said latex polymer comprises a styrene-isobutylene copolymer.

IX. Evidence Appendix

None.

X. Related Proceedings Appendix

None.